K003324
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510(k) Summary of Safety and Effectiveness

DEC 0 6 2001

(1) Submitter's name: Encore Orthopedics®, Inc.
Submitter's address: 9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number: 512-834-6255
Contact Person: Joanna Droege
Date summary prepared: September 6, 2001

(2) Trade or proprietary device name: Plasma Sprayed Shoulder
Common or usual name: Cemented Shoulder Prosthesis
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

(3) Legally marketed predicate device: Encore Total Shoulder (K950651)
Encore Grit Blasted Humeral Stems (K991603)
Biomet Bio-Modular Shoulder (K992119)

(4) Subject device description:

This system includes a humeral stem, head and glenoid component and is to be used with bone cement. These devices are intended to aid the surgeon in relieving the patient of shoulder pain and restoring shoulder motion.

The Plasma Sprayed Shoulder consists of a humeral stems (sizes 6, 8, 10, 12, 14, 16) with a neck angle of 135 degrees. The Plasma Sprayed Shoulder is available in 101-200mm lengths. The humeral stem is manufactured from wrought/forged titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. The proximal body of the stem is plasma sprayed.

The humeral stem is trapezoidal in proximal cross-sectional geometry with a cylindrical distal portion. Anterior and lateral fins are located on the proximal body to help provide rotational stability. The lateral fin has suture holes to allow reattachment of soft tissue and bone fragments in the case of proximal humeral fracture.

The Plasma Sprayed Shoulder is to be used in conjunction with the humeral head and glenoid components cleared in K950651.

(5) Subject device intended use:

The Plasma Sprayed Shoulder is intended for total shoulder arthroplasty inserted with bone cement. The indications for use include: non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, revision where previous devices or treatments have failed, correction of functional deformity, treatment of acute fracture of the humeral head unmanageable using other treatments, and cuff tear arthroplasty.

(6) Performance data:

The Food and Drug Administration have established no performance standards applicable to total shoulder prostheses.

(7) Basis for substantial equivalence:

The Plasma Sprayed Shoudler is substantially equivalent to Encore Total Shoulder, Encore Grit Blasted Humeral Stems, and Biomet Bio-Modular Shoulder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Ms. Joanna Droege
Regulatory/QA Engineer
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K003324
Trade/Device Name: Plasma Sprayed Shoulder
Regulation Number: 21 CFR §888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: September 6, 2001
Received: September 7, 2001

Dear Ms. Droege:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003324

Device Name: Plasma Sprayed Shoulder

Indications For Use:

Plasma Sprayed Shoulder
Indications For Use

The Plasma Sprayed Shoulder is intended for total shoulder arthroplasty inserted with bone cement. The indications for use include: non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, revision where previous devices or treatments have failed, correction of functional deformity, treatment of acute fracture of the humeral head unmanageable using other treatments, and cuff tear arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003324